K041222
1 of 2

OCT 14 2004

7.0 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92."

SUBMITTER:

B. Braun Medical Inc.
1601 Wallace Drive, Ste 150
Carrollton, TX 75006-6690
(972) 245.2243

Contact: Linda Morgan, RN, Senior Regulatory Affairs Specialist

DEVICE NAME:

Pinnacle™ TPN Management System Transfer Set

COMMON OR USUAL NAME:

I.V. Fluid Transfer Set

DEVICE CLASSIFICATION:

Class II per Code of Federal Regulations, Title 21, § 880.5440, Intravascular Administration Sets, product code LHI and NEP

PREDICATE DEVICES:

Baxa Corporation
Exacta-Mix™ 2400 Compounding System Administration Set,
K002705

Baxter Healthcare Corporation
Automix® 3+3/AS Compounder Transfer Set,
K961008

DESCRIPTION:

The Pinnacle™ TPN Management System Transfer Set is available in a 6-lead or a 9- lead configuration with vented or non-vented spikes. The detachable lipid line may be used when compounding lipid formulations into a dual-chambered final container.

Pinnacle™ TPN Management System
Transfer Set

The Pinnacle™ TPN Management System Transfer Set is to be used with the Pinnacle TPN Management System, a gravimetric pharmacy compounding device.

INTENDED USE:

The Pinnacle™ TPN Management System Transfer Set is intended to be used with the Pinnacle TPN Management System gravimetric pharmacy compounding device in the pharmacy to provide a sterile fluid path for the compounding of ingredients from multiple source containers into a final container.

SUBSTANTIAL EQUIVALENCE:

The Pinnacle™ TPN Management System Transfer Set is similar in intended use, operation and function to Exacta-Mix 2400 Compounding System Administration Set, distributed by Baxa Corporation, K002705, and the Automix 3+3/AS Compounder Transfer Set, distributed by Baxter Healthcare corporation, K961008.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 14 2004

Ms. Linda Morgan, RN
Sr. Regulatory Affairs Specialist
B. Braun Medical, Incorporated
1601 Wallace Drive, Suite 150
Carrollton, Texas 75006-6690

Re: K041222
Trade/Device Name: Pinnacle™ TPN Management System Transfer Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: LHI
Dated: August 26, 2004
Received: August 27, 2004

Dear Ms. Morgan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

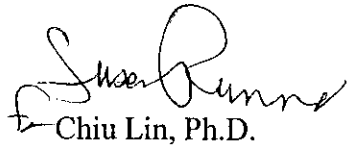
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K041222

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Pinnacle™ TPN Management System
Transfer Set

2.0 Indications for Use Statement

510(k) Number (if known): K041222

Device Name: Pinnacle™ TPN Management System Transfer Set

Indications For Use:

The Pinnacle Transfer Set is intended to be used with the Pinnacle TPN Management System gravimetric pharmacy compounding device in the pharmacy to provide a sterile fluid path for the compounding of ingredients from multiple source containers into a final container.

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K041222